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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/601,223 02/14/96 MCALFAR

J SELF, P-005-11
EXAMINER

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AIM1/0123

ART UNIT PAPER NUMBER
BELL, D 7

1102
DATE MAILED:

01/23/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☒ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-35 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-35 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Serial Number: 08/601223

-2-

Art Unit: 1102

Specification

1. The disclosure is objected to because of the following informalities:

Page 10, line 22; Change --two-- to --to--.

Page 11, line 4; After --device--, Insert --in--.

Page 14, line 12; Change --heat ed-- to --heated--.

Page 15, line 7; Change --An-- to --A--.

Page 18, line 6; Change --nvention-- to --invention--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claims 1-35 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the filler being silica. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Applicant has disclosed that a filler is used in the device, however, the only example that is disclosed is silica. No other examples have been disclosed showing that all fillers will work in this apparatus.

3. Claims 8-12, 33-35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1102

Claim 8 is vague and indefinite with respect to the use of a trademark or tradename used in the claim. The use of these terms in a claim are not permissible, since a change in the formulation is at the whim of the manufacturer. The generic name is acceptable.

Claims 33-35 are vague and indefinite with respect to whether the applicant is claiming the apparatus or the method of using the apparatus. It appears that there is no structural features recited in the instant claims as set forth, but instead are only process limitations. Correction or clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Art Unit: 1102

Evaluations of the level of ordinary skill in the art requires consideration of such factors as various prior art approaches, types of problems encountered in the art, rapidity with which innovations are made, sophistication of technology involved, educational background of those actively working in the field, commercial success, and failure of others.

The "person having ordinary skill" in this art has the capability of understanding the scientific and engineering principles applicable to the claimed invention. The evidence of record including the references and/or the admissions are considered to reasonably reflect this level of skill.

4. Claims 1-35 are rejected under 35 U.S.C. § 103 as being unpatentable over Ikeda et al (5565085 or 5582697) in combination with Flaherty et al 5582698).

Ikeda et al (5565085 or 5582697) disclose a biosensor for quantifying a substrate in a sample solution, wherein a reaction layer or working coating is disposed over a working electrode and contains an enzyme, mediator and aqueous solution of CMC. See abstracts; col. 3, lines 1-32 of 5565085; and Example 1 of 5582697.

Ikeda et al does not teach the use of a filler such as silica in the working coating disposed over the working electrode.

Flaherty et al discloses the use of a silica filler in a semipermeable membrane to increase strength and storage stability. See col. 19, lines 46-63. The membrane with such a filler is also well known for its ability to allow glucose and oxygen permeability. See col. 18, lines 26-46.

Art Unit: 1102

The subject matter as a whole would have been obvious to one having ordinary skill in the art at the time the instant invention was made because even though the prior art of Ikeda et al does not disclose the use of silica in the working coating, the prior art of Flaherty et al shows that the addition of silica into a membrane for strength and stability reasons is well within the ability of the skilled artisan. Incorporation of a carrier of diluent (i.e. filler) has been held to be obvious. See In re Lerner, 169 USPQ 51. The recitations in the claims with respect to the conductive base being carbon and the working coating including an enzyme and mediator are taught in the prior art of Ikeda et al. The recitation in the claims with respect to the amounts of each component in the coating composition is within the ability of the skilled artisan, and is dependent upon the intended use of the particular sensor and can be determined and optimized for each use by routine optimization techniques. The prior art of Ikeda et al shows that the second coating is always absent of the enzyme material, and since the materials for both coatings are the same except for this aspect of using the enzyme, one having ordinary skill in the art would know~~x~~ that when you use a filler in working coating, you would also use the filler in the other coating so that the measurement accuracy will be obtained and not flawed by differences in the reference membrane being used. It appears to the examiner that since silica is being

Serial Number: 08/601223

-6-

Art Unit: 1102

used in the prior art of Flaherty, that the surface regions of the working coating will be hydrophobic and hydrophilic and therefore this aspect of the invention appears to have been met absent evidence to the contrary. The binder of hydroxyethylcellulose is considered obvious since the prior art of Ikeda discloses CMC which is a binder, and one binder is every bit as good as another absent evidence to the contrary. Further this material is known in the art to be conventional and the two materials are known to be functional equivalents of one another. The method of making the disposable test strip is shown in the prior art of Ikeda et al and is therefore considered to be an obvious way of making the device. The claims 33-35 have been rejected over the prior art above since it is unclear as to what the structure of the device is that the applicant is instantly claiming.

Therefore, the prior art of Ikeda et al (either patent) in combination with Flaherty et al render the applicants instant invention as obvious for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Bell whose telephone number is (703) 308-2527. The examiner can normally be reached on Monday thru Thursday from 6:30 AM to 5:00 PM.

Serial Number: 08/601223

-7-

Art Unit: 1102

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathryn Gorgos, can be reached on (703) 308-3328. The fax phone number for this Group is (703) 305-3599.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661.

BFB

January 19, 1997


BRUCE F. BELL
PRIMARY EXAMINER
GROUP 1100